



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/243,342	05/16/94	BUCALA	R 7815008

08/243,342 05/16/94 BUCALA

HM31/0608

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EXAMINER	
MARSCHEN, A	
PAPER NUMBER	

DATE MAILED:

06/08/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.
08/243,342

Applicant(s)
Bucala et al.

Examiner
Marschel, Ardin

Group Art Unit
1634



☒ Responsive to communication(s) filed on Mar 13, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 63, 80-82, and 84-90 is/are pending in the application.

~~Previously~~ ☒ Claim(s) 1-62, 64-79, 83, and 91-93 have been canceled. ~~Claim(s) 1-62, 64-79, 83, and 91-93 have been canceled.~~

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 63, 80-82, and 84-90 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1634.

Applicants' arguments, filed 3/13/98, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because the specification contains sequences that fall under these rules without a SEQ ID NO. cited therewith. For example, on page 29, lines 18 and 21, sequences are cited without SEQ ID Nos. as required with such citations. Other sequences are given in the specification without SEQ ID NOs., such as, for example, on page 55, lines 33 and 34, and on page 88, lines 1-9. Applicants argue against this requirement by pointing to a previously submitted sequence amendment. This is not persuasive in overcoming this requirement because the above sequence citations lack the appropriate SEQ ID NOs. and not because there was or was not a previously submitted sequence amendment. Applicants are given the same response time regarding

this failure to comply as that set forth to respond to this office action.

Claims 63, 80-82, and 84-90 are rejected, as discussed below, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is reiterated and maintained from the previous office action, mailed 10/8/97. Applicants firstly argue that the 103(a) rejection herein maintained documents the enablement of the claimed invention. In response the requirements of 35 U.S.C. § 112, first paragraph, include the requirement that an invention be described in full, clear, concise, and exact terms. This is a higher standard than required for a 103(a) rejection which only needs to document that the prior art discloses the practice of the invention sufficiently clearly to make it obvious to practice with a reasonable expectation of success. Enablement requires that the invention be described such that it is not an invitation to perform undue experiment but rather disclosed such that a reasonable predictability is achieved for practicing the invention. The applicants' specification clearly invites undue experimentation because of only giving general guidance leaving up to the practitioner the huge task of designing antisense oligomers via balancing the multitude of parameters as summarized

in the previous office action. Applicants stated in arguments that the Examiner "goes on about all kinds of experiments". It is noted that applicants have not argued nor suggested that these "all kinds of experiments" are unnecessary. Applicants then argue that early filing of inventions is encouraged by the case law. This is acknowledged. If, however, the invention is filed only in the concept stage without reasonable enablement, by which to reduce the invention to practice it fails to meet the requirements of 35 U.S.C. § 112, first paragraph. It is noted that research projects, as instantly disclosed, are commonly and frequently considered in the scientific community, but that enablement requires more. It requires the disclosure of sufficient guidance to practice the invention so as to result in predictable results. It is noted that the instant disclosure lacks a suggestion as to even the first segment of the MIF gene sequence to test regarding designing an antisense oligomer. Applicants also argue that no case law has been cited by the Examiner. In response the Examiner believes that 35 U.S.C. § 112, first paragraph, is sufficiently clear on this issue at this time combined with the well known interpretation of this statute regarding an invitation to experiment as lacking in enablement. Some case law citations will be cited up in the future if applicants are unaware of the "invitation to experiment" basis for a lack of enablement rejection.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this

Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 63, 80-82, and 84-90 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bernhagen et al. (ref. BU) taken in view of Uhlmann et al. (ref. BA) and Clark et al. (ref. CD).

This rejection is maintained and reiterated from the previous office action, mailed 10/8/97. Applicants have alleged that the priority date for the instant invention is 5/17/93 which predates the Bernhagen et al. reference. This priority claim is based on the alleged pages 26-31 of parent application serial

number 08/063,399. Since applicants have not reproduced these pages of this priority application, their allegation of priority is without factual support at this time and therefore, non-persuasive in overcoming this rejection. The priority application file, however, has been requested by the Examiner but has not been received as of the mailing of this office action. It will be reviewed regarding this issue when the priority application is received by the Examiner.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

June 8, 1998

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER